

## **STEERABLE GUIDE CATHETER WITH PRE-SHAPED ROTATABLE SHAFT**

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### **FIELD OF THE INVENTION**

The invention relates generally to guide catheters, and more particularly to dual-sheath, telescoping guide catheters having a steerable outer sheath and  
10 pre-formed inner sheath used to locate and cannulate the coronary sinus of a patient's heart.

### **BACKGROUND OF THE INVENTION**

15 Guiding catheters are instruments that allow a physician to locate and cannulate vessels in a patient's heart for performing various medical procedures, including venography and implanting of cardiac pacing devices. Cannulating heart vessels requires navigating a small diameter, flexible guide through the convoluted vasculature into a heart chamber, and then into a destination heart  
20 vessel. Once the destination heart vessel is reached, the catheter acts as a conduit for insertion of payloads into the vessel.

A commonly accessed destination vessel for cardiac pacing lead insertion is the coronary sinus. A pre-shaped guiding catheter is typically used to blindly locate the coronary sinus ostium. This endeavor, however, is complicated by the  
25 fact that the location of the coronary sinus ostium may vary appreciably from one patient to another, especially among patients with diseased hearts. Oftentimes, the clinician is entirely unable to locate the coronary sinus ostium using the guiding catheter, and must resort to finding the ostium by "mapping" (interpreting localized bipolar waveforms) using an electrophysiological (EP) catheter and an  
30 ECG monitor. After the ostium is located, the guiding catheter is typically used to

inject radiographic contrast media into the coronary sinus to highlight the associated venous system, and then a pacing lead is installed within one of the coronary branches.

Complicating this scenario is the dynamic structural deformation of the

5 heart chambers that occurs from normal cardiac activity during the procedure. This further increases the difficulty of guiding a catheter to its destination.

Presently, a considerable amount of time is often spent by the physician when manipulating such catheters within cardiac structures, such as the right atrium, simply trying to locate an anatomical feature of interest, such as the coronary

10 sinus ostium.

Guiding catheter systems are typically configured with a profile that is optimized for the intended method of access. In the case of accessing the coronary sinus via the right atrium, a catheter with a distal contour including a relatively sharp bend will point the catheter towards the likely location of the

15 coronary sinus once the right atrium is reached. The contours of pre-shaped guiding catheters are generally fixed, and this is typically achieved in production by constraining the distal end within a shaping fixture while warming them until they assume the intended shape (i.e., by “heat setting” their polymer shaft).

A fixed shape catheter is adequate in many cases where the pathway is

20 not significantly convoluted and the pathway does not deviate significantly between patients. In situations where structural anomalies or significant variations exist, use of a fixed shape catheter may require that the clinician stock multiple size and shapes of catheters to account for potential variations. Fixed shape catheters may require a time consuming trial and error process of inserting

25 and removing different shapes until the destination vessel is successfully accessed.

There is a need for an improved guide catheter for accessing heart vessels that can dynamically account for anatomical variations and defects associated with the destination structures. The present invention fulfills these

and other needs, and addresses other deficiencies of prior art implementations and techniques.

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## SUMMARY OF THE INVENTION

The present invention is directed to a guide catheter for cannulating a vessel of a patient's heart. According to one embodiment of the invention, a guide catheter includes an outer sheath having an open lumen and a pre-shaped distal end. An inner sheath having an open lumen is disposed within the open lumen of the outer sheath. The inner sheath is axially rotatable and longitudinally translatable relative to the outer sheath. The pre-shaped distal of the inner sheath conforms to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assumes a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath. A steering tendon is disposed along the outer sheath. A distal end of the steering tendon is connected to a distal tip of the outer sheath. A guide handle is connected to a proximal end of the outer sheath. A steering mechanism is disposed on the guide handle. The steering mechanism is connected to a proximal end of the steering tendon. The steering mechanism provides a pulling force on the steering tendon to adjustably change an angle of the pre-shaped distal end of the outer sheath.

In one configuration, the steering mechanism includes a steering handle pivotably connected to the guide handle. In another aspect, the outer sheath may further include at least one longitudinally displaced pre-stress line extending from the proximal end to the distal tip of the outer sheath. Similarly, the inner sheath may further include at least one longitudinally displaced pre-stress line extending from a proximal end to a distal tip of the inner sheath.

The guide catheter may be configured with at least one electrode on the distal end of one the inner sheath. At least one electrical conductor can be coupled to the electrode(s), the conductor(s) being disposed within the inner sheath. Similarly, another configuration includes at least one electrode on the pre-shaped distal end of the outer sheath, with at least one electrical conductor coupled to the electrode(s), the conductor(s) disposed within the outer sheath. The guide catheter may also include an occlusion device connected to the distal end of the inner sheath. An occlusion device may also be connected to the pre-shaped distal end of the outer sheath. In another configuration, at least one pressure sensing device is connected to the distal end of the inner sheath. At least one electrical conductor is coupled to the pressure sensing device(s), the conductor(s) being disposed within the inner sheath. At least one pressure sensing device can also be connected to the pre-shaped distal end of the outer sheath. At least one electrical conductor is coupled to the pressure sensing device(s), the conductor(s) being disposed within the inner sheath.

In a particularly useful configuration of the guide catheter, the pre-shaped distal end of the outer sheath includes a substantially straight section at the distal tip of the outer sheath with a length of about 1 cm to about 5 cm. Proximally adjacent the straight section is a substantially circular curve having a bend radius ranging from about 0 degrees to about 180 degrees and a bend radius ranging from about 1 cm to about 7 cm.

The inner sheath may also include a substantially straight section at the distal tip having length of about 0.5 cm to about 4.0 cm. Proximally adjacent the straight section is a substantially circular curve. The curve has a bend radius ranging from about 0 degrees to about 150 degrees and a bend radius ranging from about 1 cm to about 5 cm.

The steering tendon may be disposed on an outer surface of the outer sheath. Alternatively, the steering tendon may be disposed within the open lumen of the outer sheath. In yet another configuration, the outer sheath may

further include a second lumen, and the steering tendon is disposed within the second lumen.

In another embodiment of the present invention, a method of inserting a payload into the coronary sinus of a patient's heart involves providing a guide catheter. The guide catheter includes an outer sheath having an open lumen and a pre-shaped distal end. An inner sheath having an open lumen and a pre-shaped distal end is disposed within the open lumen of the outer sheath. The inner sheath is axially rotatable and longitudinally translatable relative to the outer sheath. The pre-shaped distal of the inner sheath conforms to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assumes a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath. A steering tendon is disposed along the outer sheath. A distal end of the steering tendon is connected to a distal tip of the outer sheath. A guide handle is connected to a proximal end of the outer sheath. A steering mechanism is disposed on the guide handle. The steering mechanism is connected to a proximal end of the steering tendon. The steering mechanism provides a pulling force on the steering tendon to adjustably change an angle of the pre-shaped distal end of the outer sheath.

The method further involves inserting a distal end of the catheter through the patient's right atrium via an access vessel. The inner sheath is distally extended from the outer sheath, the distal end of the inner sheath assuming a pre-formed shape upon extension from the outer sheath. A pulling force is provided on the steering tendon to adjustably change an angle of the pre-shaped distal end of the outer sheath, the inner sheath axially rotated relative to the outer sheath, and the inner sheath longitudinally translated relative to the outer sheath to direct the distal end of the inner sheath for finding and cannulating the patient's coronary sinus. The payload is then advanced through the open lumen of the inner sheath until the payload is inserted into the patient's coronary sinus.

Another embodiment of the method involves distally advancing the outer sheath over the inner sheath to seat the outer sheath in the coronary sinus after finding and cannulating the patient's coronary sinus. The inner sheath is proximally retracted to remove the inner sheath from the outer sheath. The 5 payload is then advanced through the open lumen of the outer sheath to insert the payload into the patient's coronary sinus.

In one aspect of the previously described methods, the payload includes a pacing lead. The methods may also include injecting a contrast media into the open lumen of the inner sheath for venography after finding and cannulating the 10 patient's coronary sinus. In one configuration, the outer sheath of the catheter further comprises at least one longitudinally displaced pre-stress line extending from the proximal end to the distal tip of the outer sheath. In this case, the methods further comprise splitting the outer sheath while retracting the outer sheath in a proximal direction to remove the outer sheath after inserting the 15 payload through the open lumen of the inner or outer sheaths.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed 20 description and claims taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an external view of a catheter embodying features of the present invention and illustrating longitudinal translation of an inner sheath relative to an outer sheath;

5 Figure 2 is an external view of the catheter shown in Figure 1 illustrating the inner sheath rotating within the outer sheath;

Figure 3A is an external view of the catheter shown in Figure 1 further illustrating a deflection of a pre-shaped distal end of the outer sheath

10 Figure 3B is cross section view of Section 1-1 from Figure 3A;

Figure 4 is a cut-away view of a patient's heart, showing a catheter embodying features of the present invention deployed within the heart;

Figure 5 is an external view of a catheter illustrating a peel-away outer sheath according to an embodiment of the present invention;

15 Figure 6 is an external view of a catheter containing a pacing lead within the outer sheath according to an embodiment of the present invention;

Figure 7 is a view of the distal end of a catheter showing an occlusion balloon attached to the inner sheath according to an embodiment of the present invention; and

20 Figure 8 is view of the distal end of a catheter illustrating electrodes on the distal tip of the inner sheath according to an embodiment of the present invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and 25 will be described in detail herein. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

## DETAILED DESCRIPTION OF THE VARIOUS EMBODIMENTS

5        In the following description of the illustrated embodiments, references are made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration, various embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope  
10      of the present invention.

With reference to Figure 1, a guide catheter is shown embodying features of the present invention. The guide catheter includes an inner sheath 1, an outer sheath 2, and a guide handle 3. The guide handle 3 is connected to a proximal end of the outer sheath 2. The guide handle 3 can include a homeostasis device  
15      that provides a seal between the inner and outer sheaths 1, 2. The outer sheath 2 contains an open lumen 2A, and the outer sheath 2 is typically elongated and flexible. The outer sheath 2 is also adjustably deflectable at a distal end. The inner sheath 1 is movably disposed within the open lumen 2A of the outer sheath 2 such that the inner sheath 1 can translate longitudinally and rotate axially within  
20      the outer sheath 2.

The inner sheath 1 is typically more flexible than the outer sheath and includes a pre-formed distal shape 4. The more flexible inner sheath 1 conforms to the shape of the outer sheath 2 when a substantial portion of the inner sheath's distal end is contained within the outer sheath 2. When the inner sheath  
25      1 is sufficiently extended, the distal end of the inner sheath 1 assumes its pre-formed distal shape 4, as indicated by phantom lines in Figure 1.

The inner sheath 1 can be formed of a polymeric tube. Pebax is a polymer typically used in this application, although other materials such as nylon and PVC may be employed. Constructing the inner sheath 1 from a multi-

layered tube having a metallic braid may be desirable in some applications where greater stiffness is required. The pre-formed distal shape 4 can be thermoset during manufacture of the inner sheath 1.

The inner sheath 1 has an open lumen 1A that can receive a payload. An  
5 inner lubricous lining made of a material such as PTFE can be provided within the open lumen 1A. The lubricious liner helps to ease advancement of payloads through the open lumen 1A. An inner sheath 1 used in coronary sinus cannulation procedures may have an inner lumen diameter of about 0.030 inches to about 0.100 inches, depending on the size of payloads and/or guide members  
10 that are intended to pass through or otherwise be disposed within the open lumen 1A.

The ability of the inner sheath 1 to assume a pre-formed distal shape 4 upon inner sheath extension is advantageous for accessing vessels within a patient's heart. For example, when accessing the patient's coronary sinus, a  
15 commonly traversed pathway is through a percutaneous access vessel such as the left subclavian, then through the superior vena cava and into the right atrium of the heart. This pathway is a relatively large, smooth curve, and outer sheath 2 can be shaped to accommodate the pathway. The inner sheath 1 can be retracted within the outer sheath 2 while the guide catheter is being advanced  
20 through the pathway, allowing the guide catheter to substantially assume the shape of the outer sheath 2.

Once the distal end of the catheter has entered the right atrium, a relatively sharp transition is desirable to access the coronary sinus ostium. The inner sheath 1 can now be extended to provide such a transition. Extension of  
25 the inner sheath 1 past the distal tip of the outer sheath 2 allows the distal end of the inner sheath 1 to assume its pre-formed distal shape 4. The pre-formed distal shape 4 can have dimensions that are optimized for locating the coronary sinus ostium, in this example. Axial rotation and longitudinal extension of the inner sheath 1 within the outer sheath 2 beneficially allows the distal end of the

inner sheath 1 to account for variations within the right atrium while searching for the ostium.

Figure 2 illustrates the maneuverability provided by the rotatable inner sheath 1. The inner sheath 1 is axially rotatable within the outer sheath 2.

- 5 Rotation of the inner sheath 1 is typically performed by grasping a proximal section of the inner sheath 1 and applying a torque to the inner sheath 1 while restraining the outer sheath 2. To assist in applying a torque, an attachment may be provided on the proximal end of the inner sheath 1, such as a wing luer 5, shown in Figure 2. The curved arrows in Figure 2 show the effect on the distal 10 end of the inner sheath 1 caused by rotating the wing luer 5. Phantom lines at the distal end of the inner sheath 1 illustrate various rotated orientations of the inner sheath 1.

To provide further advantages with respect to accessing vessels within a heart chamber, the outer sheath 2 is adjustably deflectable. Referring to Figure 15 3A, the deflectability of the outer sheath 2 is illustrated. The guide catheter includes a steering tendon 7 disposed within the outer sheath 2. The steering tendon 7 is attached to the distal end of the outer sheath 2, as shown in the detail drawing of Figure 3A. In one configuration, the steering tendon 7 is attached by bonding or embedding a semicircular plate 8 near the outer sheath distal tip. The 20 steering tendon 7 is fixably attached to the semicircular plate 8. Applying a tensile force on the proximal end of the steering tendon 7 changes a shape of the deflects the distal tip of the outer sheath 2.

A steering handle 6 may be attached to the guide handle 3 to enable 25 adjustably applying a tensile force to the steering tendon 7. The steering handle 6 is typically pivotably mounted on the guide handle 3, and may include a friction or lock mechanism to hold the steering handle 6 at a fixed position.

To aid in the action of the steering tendon 7, the outer sheath 2 may include a pre-formed distal end 9. The pre-formed distal end 9 can be optimally shaped for advancement through heart chambers or intended venous pathways.

The pre-formed distal end 9 may also determine the deflection point of the outer sheath 2 upon application of a tensile force to the steering tendon 7.

As shown in Figure 3A, the outer sheath 2 has an initial shape at the pre-formed distal end 9. The direction of motion of the outer sheath 2 as it is deflected by the steering tendon 7 and steering handle 6 is indicated by the bold arrows. The deflected positions of the steering handle 6 and outer sheath 2 are indicated in phantom lines. The steering tendon 7 affects a bend angle and a bend radius of the pre-formed distal end 9, thereby enabling deflection of a distal tip of the guide catheter.

The outer sheath 2 may be formed of a polymeric tube similar to the inner sheath 1. The outer sheath 2 is typically stiffer than the inner sheath 1, and may benefit from a multilayer construction that includes a metallic braid or coil. An inner lubricous lining made of PTFE or equivalent material can be provided within the outer sheath lumen 2A to reduce friction between the inner and outer sheaths 1, 2. The steering tendon 7 can be disposed within the outer sheath lumen 2A. The steering tendon 7 can also be disposed along an outer surface of the outer sheath 2. Alternatively, the outer sheath 2 can contain a second lumen 21 as seen in Figure 3B. The steering tendon 7 is deployed within the second lumen 21. The steering tendon 7 may be formed of a metallic wire or ribbon, although other tensile members such as a high strength polymer fiber can also be employed with similar results.

A catheter embodying features of the present invention is particularly useful in applications such as implanting pacing and defibrillation leads into heart vessels. This procedure is illustrated Figure 4. In such an application, the distal end of the catheter is typically introduced through a percutaneous access point 10, such as in the left cephalic vein or left subclavian vein. The inner sheath 1 can be retracted within the outer sheath 2 while the catheter is advanced through the access vessel into to the heart. As shown this example the catheter advances through the superior vena cava into the right atrium 11. In some

cases, a guide wire 13 may be inserted through the venous pathway before the catheter is introduced, and the catheter then advanced over the guide wire 13 into the right atrium.

Once the distal tip of the outer sheath 2 has reached the right atrium, the  
5 inner sheath 1 can be extended. The inner sheath 1 is extended and rotated to locate the coronary sinus ostium 12. Additional assistance in finding the ostium 12 is provided by deflecting the outer sheath 2 via the steering tendon 7. Once the inner sheath 1 has located the ostium 12, the inner sheath 1 can be advanced as far as required into the coronary sinus.

10 If a guide wire 13 was introduced prior to inserting the catheter, the guide wire 13 can be advanced through the inner sheath 1 into the coronary sinus. The guide wire 13 is then distally extended beyond the inner sheath 1 into a branch of the coronary sinus. The guide wire 13 can then be used to guide a pacing lead 14 into the branch vessel. The pacing lead 14 is advanced through the inner  
15 sheath 1 and seated into the branch of the coronary sinus.

At this point in the procedure, it may be desired to remove at least the outer sheath 2. In one configuration, the outer sheath 2 can be made with a peel away feature. Turning to Figure 5, a peel away feature may include one or more longitudinal pre-stress lines 15 extending from proximal to distal ends along the  
20 outer sheath 2. The advantages of a peel-away feature include the ability to proximally remove the outer sheath 2 over the inner sheath 1 seated without disturbing any proximal attachments on the inner sheath 1. Proximal attachments on the inner sheath 1 may include a wing luer 5.

A peel-away feature of the outer sheath 2 in a catheter according the  
25 present invention can further include the ability of the guide handle 3 to separate into at least two sections. As seen in Figure 5, application of forces to the separation grips 16 can split the guide handle 3. The guide handle 3 is connected to the outer sheath 2, so guide handle separation can initiate outer sheath separation as well. Further details of exemplary peel-away features are

disclosed in commonly owned U.S. application entitled "Telescoping Guide Catheter With Peel-Away Outer Sheath" and identified under attorney docket 1275.37US01, which is hereby incorporated herein by reference.

In some cases, it may be desirable to remove the inner sheath 1 prior to  
5 introducing the pacing lead 14. In such a case, the pacing lead 14 is advanced  
through the outer sheath 2. This may be desirable as the outer sheath lumen 2A  
is larger than that of the inner sheath 1. In this scenario, the outer sheath 2 is  
distally advanced over the inner sheath 1 until the outer sheath 2 is seated in the  
coronary sinus. The inner sheath 1 is then proximally retracted and removed,  
10 whereupon pacing lead insertion can proceed through the outer sheath 2.

This situation is illustrated in Figure 6, where the pacing lead 14 is shown  
extending from the distal end of the outer sheath 2. The outer sheath 2  
illustrated in Figure 6 also employs a distally mounted occlusion balloon 15. The  
occlusion balloon 15 can be inflated when the outer sheath 2 is in a vessel where  
15 blockage of blood flow is desired. Blood flow can be temporarily occluded in this  
way before injecting a contrast media, for example. The occlusion balloon 15 is  
typically inflated by a fluid injected from a proximal end of the outer sheath 2.  
Methods of mounting and actuating the occlusion balloon 15 are well known in  
the art.

20 Figure 7 illustrates an occlusion balloon 16 mounted on the distal end of  
the inner sheath 1. Actuation and disposition of the occlusion balloon 16 is  
similar to that described for the occlusion balloon 15 mounted on the outer  
sheath 2.

Another useful configuration of a guide catheter according to the present  
25 invention includes attaching electrodes to a distal end of the guide catheter.  
Figure 7 shows electrodes 17 mounted on the distal end of the outer sheath 2.  
The electrodes 17 are typically flush mounted, and are connected to at least one  
conductor 18 that is disposed between the distal and proximal ends of the inner  
sheath 1.

Figure 8 shows electrodes 19 mounted on the inner sheath 1 in a similar fashion as the electrodes 17 on the outer sheath 2. The electrodes 19 are connected to at least one conductor 20 that is disposed within the inner sheath 1. It is understood the electrodes may be disposed on both the inner and outer

5 sheaths 1, 2 in certain configurations.

The electrodes 17, 19 can be used for electrophysiological (EP) purposes, such as EP mapping structures within the heart. EP electrodes are often fabricated from stainless steel, although the electrodes 17, 19 could be made of platinum, silver or other electrode materials known in the art. A guide catheter

10 according to the present invention can also be adapted to use ablation electrodes. Ablation electrodes are typically formed of platinum/iridium, and can be mounted as previously described and illustrated in Figures 7 and 8.

Another adaptation of a catheter according to the present invention includes attaching one or more pressure sensing devices to at least the distal

15 end of the inner and/or outer sheaths 1, 2. A pressure sensor, for example, can detect dynamic characteristics of blood flow, including fluid velocity. Tubular piezoelectric sensors can be configured to sense pressure on the inner sheath 1, and can be deployed in a similar manner to the electrodes 19 shown in Figure 8. As with the electrodes 19, at least one conductor 20 would be coupled to the

20 pressure sensing device and disposed within the inner or outer sheath 1, 2. Other sensors that can be similarly incorporated on the inner and outer sheaths 1, 2 include a temperature sensor, activity sensor (e.g. accelerometer) or oxygen sensor.

It will, of course, be understood that various modifications and additions

25 can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.